cephalothin sodium aqueous stock solutions serially diluted with distilled water to contain approximately the following concentrations: 2,560, 1,280, 640, 320, 160, 80, and 40 micrograms of cephalothin per milliliter. The potency of each diluted solution is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of micrograms of cephalothin that it is represented to contain. The pH of the solution containing 2,560 micrograms of cephalothin per milliliter is not less than 4.2 and not more than 7.0. The cephalothin used conforms to the standards prescribed by §442.25a(a)(1) (i), (v), (vi), (vii), (viii), and (ix) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 5 milliliters.

(b) *Tests and methods of assay.* The sample solutions used for testing must be thawed and brought to room temperature before testing.

(1) *Potency.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 microgram of cephalothin per milliliter (estimated).

(2) *pH.* Proceed as directed in §436.202 of this chapter, using the solution containing 2,560 micrograms of cephalothin per milliliter.

§460.119 Chloramphenicol concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chloramphenicol concentrated stock solutions for use in preparing susceptibility test panels are frozen aqueous chloramphenicol stock solutions serially diluted with distilled water to contain approximately the following concentrations: 1,280, 640, 320, 160, 80, 40, and 20 micrograms of chloramphenicol per milliliter. The potency of each diluted solution is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of micrograms of chloramphenicol that it is represented to contain. The pH of the solution containing 1,280 micrograms of chloramphenicol per milliliter is not less than 4.5 and not more than 7.5. The chloramphenicol used conforms to the standards prescribed by §455.10(a)(1) (i), (iii), (iv), (v), (vi), and (vii) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 5 milliliters.

(b) *Tests and methods of assay.* The sample solution must be thawed and brought to room temperature before further testing.

(1) *Potency.* Proceed as directed in §436.106 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with distilled water to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

(2) *pH.* Proceed as directed in §436.202 of this chapter using the solution containing 1,280 micrograms of chloramphenicol per milliliter.

§460.122 Clindamycin concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clindamycin concentrated stock solutions for use in preparing susceptibility test panels are frozen aqueous clindamycin hydrochloride stock solutions serially diluted with